UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

September 16, 2016

MEMORANDUM

Subject: Efficacy Review of Additional Study for Mold Killing Primer; EPA File Symbol No. 69587-A; DP Barcode: D435426

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Applicant: Rust-Oleum Corporation
11 Hawthorn Parkway,
Vernon Hills, IL 60061

Formulation from the Label:

Active Ingredient	% by wt.
3-Iodo-2-Propynyl Butyl Carbamate	0.15 %
Other Ingredients:	99.85 %
Total	100.00 %

(5000ppm available chlorine)

I. BACKGROUND

The product, Mold Killing Primer (EPA File Symbol 69587-A), is a new product. The applicant requested to register the ready-to-use spray primer paint as a hard, non-porous surfaces mold and mildew fungicide (mold killing property). The registrant submitted, via e-mail, on May 26, 2016, a complimentary package after technical screen rejection. The previous package contained "Hard Non-Porous Mildew-Fungistatic" study, instead of, "Hard Non-Porous Mildew-Fungicidal" study, conducted on *Aspergillus niger* (ATCC 6275). The new additional package contains a draft "Fungicidal Germicidal Spray Method" using *Trichophyton mentagrophytes* (ATCC 9533), and conducted at Accuratus, located at 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121. Evaluation of the product is based on the data submitted as part of the complimentary package (study MRID 499367-01) and additional package (Lab project A20730 study without MRID).

This data package identified as D435426, contained one study (Lab project A20730 study without MRID). Statement of No Data Confidentiality Claims for the study.

II. USE DIRECTIONS

Check with all local, state and federal regulations prior to using or working with this product. Fix the source of any moisture problems prior to remediation. Do not attempt to salvage damaged or structurally unsound building materials. Consult a qualified professional to perform a thorough inspection and supply work specifications appropriate to the project.

Surface Preparation: *For applications that have existing wet, slimy, heavy soiled, gross filth, overgrowth or loose material on the substrate a pre-cleaning step is required. Physically or mechanically remove gross filth, heavy soil, overgrowth or loose material including dirt, grease and oily films before application and ensure the substrate is free of slime or excessive moisture to ensure long-term adhesion and product performance particularly on exterior surfaces. If mold or mildew needs to be removed prior to application, remove with a mildew remover that is EPA registered and let dry. Wear eye, skin, and NIOSH approved respiratory protection. Patch surface irregularities with appropriate patching compounds.

Application: Mold Killing Primer is a ready to use product. Use at room temperature (70°F) in a well ventilated area –do not use in high humidity conditions. Shake can vigorously until ball inside can rattles. Turn upside down and continue shaking for one minute – shake occasionally during use. If ball does not rattle, do not strike the can. [Contact Rust-Oleum.] Spray 10-12" from object with short dusting strokes. If valve clogs, twist and pull off spray tip and rinse it in a solvent such as mineral spirits. Do not stick pin or other object into the stem.

Mold, Mildew, Fungi, and Odor Causing Bacteria Control: Mold Killing Primer will kill all existing mold, mildew and fungal organisms. Apply Mold Killing Primer generously and uniformly, ensuring that the surface is completely coated. Allow to dry.

Coverage: Approximately [8, 12, 14, 15, 16, 18, 20] sq. ft. per can.

Drytime: Dries in minutes; topcoat in 30 minutes with latex or oil-base paints. [For optimal protection, apply a topcoat that prevents mold & mildew on the paint film within 72 hours of application.] Full adhesion and hardness develops in 7 days. [For best results allow primer to cure overnight when applying strong solvent-base topcoats.]

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use as Fungicides (Against Pathogenic Fungi, Using a Modified Method): The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data using an appropriate test. The AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray products) may be modified to conform with the appropriate elements in the AOAC Fungicidal Test. The inoculum in the test must be modified to provide a concentration of at least 10^6 conidia per carrier. Ten carriers on each of 2 product samples at LCL representing 2 different product lots must be employed in the test. Killing of the specific pathogenic fungi on all carriers is required.

IV. BRIEF DESCRIPTION OF THE DATA

1. "Fungicidal Germicidal Spray Method" for Mold Killing Primer Aerosol. Test microorganism: *Trichophyton mentagrophytes* (ATCC 9533); by Jamie Herzan. Study conducted at ACCURATUS. Study completion date – August 2, 2016. Project number: A20730.

Percentages of 3-Iodo-2-propynyl-butylcarbamate (IPBC) in tested lots according to the submitted CoA are: lot 600-075, 0.1354% and lot 600-077, 0.1301%

This study was conducted against *Trichophyton mentagrophytes* (ATCC 9533). Two lots (600-075 and 600-077) of the product, Mold Killing Primer, at the LCL, and one Aerosol Paint Control - Blank Book 600-075, were tested according to Accuratus Protocol No. RUO01040416.FGS (copy provided). The product was received ready-to-use, aerosol spray. Fetal bovine serum (FBS) was added to the inocula at a concentration of 5%, to simulate an organic soil load. Ten (10) glass slide carriers per product lot were inoculated with 0.01 ml of a conidia suspension preparation of the test organism. The carriers were dried for 33 minutes at 36.4-36.6°C and 54.1% relative humidity. Each carrier was sprayed with the test substance at a distance of 8 to 12 inches using one spray or until thoroughly wet (actual spray time used 2 seconds). For the test substance control, the surfaces of 3 carriers were sprayed with the test substance control at a distance of 8 to 12 inches using one spray or until thoroughly wet (actual spray time used 3 seconds). Following the spray treatment, each treated carrier was held at room temperature (20.6°C) and 41 % relative humidity for 10 minutes. At the end of the exposure time, the excess liquid was drained off the carrier without touching the carrier to the Petri dish or filter paper. Each treated carrier was then transferred using sterile forceps and following identical staggered intervals to 20 ml aliquots of primary neutralizing subculture medium (Sabouraud Dextrose Broth + 0.15% Lecithin + 1.0% Tween 80 (Primary and Secondary)). The vessel was shaken thoroughly. The carriers were transferred into individual secondary subcultures containing 20 ml aliquots of secondary subculture medium within approximately 25-60 minutes of the initial transfer and the vessel was shaken thoroughly. Following secondary neutralization, all carriers sprayed with test substance were scraped with a sterile device to ensure the paint is integrated in the system and to aid in organism recovery. All neutralized subcultures were incubate for 10 days at 25-30°C. The agar plate subcultures were incubated for 66-76 hours at 25-30°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. On 7/7/16 representative test and positive control subculture tubes showing growth were subcultured to Glucose Agar and incubated at 25-30°C for 4 days. The resultant growth was

visually examined and stained by lactophenol cotton blue to confirm or rule out the presence of the test organism. Controls included viability, dried carrier counts, neutralizer effectiveness, confirmation of challenge organism, and sterility. The reported average log_{10} per carrier, for the test microorganism, is: ***Trichophyton mentagrophytes* 4.30**. **Efficacy of Mold Killing Primer Aerosol - Lot 1 dosed Book 600-075 and Lot 2 dosed Book 600-077 could not be determined due to test cancellation prior to the generation of valid data.**

Notes: 1. Neutralization confirmation control failure for both lots rendered the test conducted on April 25, April 26, June 2, and 27, 2016 invalid.

2. Testings were cancelled (3 times) for contamination and neutralization confirmation control.

3. Neutralization confirmation control was not conducted on lot 2 for test conducted on 7/7/2016 which is the reported test.

V. CONCLUSION

1. The submitted draft efficacy data **do not support** the use of the product, Mold Killing Primer, as a medical fungicidal against *Trichophyton mentagrophytes* (ATCC 9533), when used as an aerosol spray on hard, non-porous surfaces in the presence of a 5% organic soil load (fetal bovine serum) at room temperature for 10 minutes contact time. **Efficacy of Mold Killing Primer Aerosol - could not be determined.**

VII. LABEL

1. The proposed label claims that the product, Mold Killing Primer (File Symbol 69587-A), is an effective mold and mildew fungicidal coating primer, **are not acceptable** as they are not supported by the applicant data.

The product demonstrated mildew-fungistatic ability for 7 days. Claims are for the control, treatment, or prevention of mold/mildew and subsequent mold/mildew growth on hard non porous surfaces. The direction for use must specify retreatment every 7days as necessary (**not practical or unrealistic**).

2. The applicant must make the following changes to the proposed label, as appropriate:

- The product name "Mold Killing Primer" is misleading and must be changed as of product supporting data submitted to the Agency is for growth control. Killing of mold was not demonstrated to the Agency. If registrant decided to keep the product name, acceptable data generated using "Glass Slide (or comparable surface) Mildew Funqicidal Test Method" must be submitted to Agency.

- Replace all fungicidal claims mold killing claims with "7-day (one week) Mold and Mildew-fungistatic claims' or "one week mold/mildew control, treatment, or prevention claims.

- Remove all bacteria killing claims.